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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/512,126 | 10/20/2004 | Jin-Hee Choi | 9717.40USWO | 8435 |
| 23552 | 7590 | 06/07/2007 | | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | EXAMINER ANDERSON, JAMES D | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/512,126

Applicant(s)

CHOI ET AL.

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 6-8,10,11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1, 4-8, 10-11 & 14 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed 4/18/2007 has been received and entered into the application. Accordingly, claims 1, 6-8 and 10-11 have been amended and claim 14 has been added.

Newly submitted claim 14 and amended claims 6-8 and 10-11 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally submitted claims were all drawn to compositions. Amended claims 6-8 and 10-11 and newly submitted claim 14 recite methods of use. Applicants' arguments that the method claims should be rejoined to the composition claims are not persuasive because the method claims were not previously presented and therefore not subject to restriction. Accordingly, it is improper to submit method claims (which could have been properly restricted if originally presented) at this point in prosecution.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-8, 10-11 and 14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In view of the above amendments, the rejection of claims 1-2, 4-8 and 10-11 under 35 U.S.C. 102(b) has been overcome and thus is withdrawn. However, upon further consideration the following rejections are newly applied and constitute the totality of issues remaining in the present application.

In light of the new rejections being applied against the pending claims this Office Action is **Non-Final**.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al. (U.S. Patent No. 5,578,641; Issued Nov. 26, 1996) (prior art of record).

The instant claims recite a composition comprising *N,N*-dimethylphytosphingosine and at least one phytosphingosine derivative selected from the group consisting of phytosphingosine, acetylated phytosphingosine, and ethylated phytosphingosine in a weight ratio of 1:1 (claim 1). Claims 4-5 recite a kit comprising the composition of claim 1.

Jackson *et al.* teach pharmaceutical compositions comprising one or more ceramide pathway intermediates or precursors (Abstract). Said intermediates or precursors comprise sphinganine, sphingosine, phytosphingosine and derivatives thereof, including the instantly claimed *N,N*-dimethylphytosphingosine (col. 3, line 40 to col. 5, line 58; see especially col. 5, lines 34-42). The reference thus contemplates compositions comprising "one or more" of the instantly claimed compounds. The compounds of the invention are incorporated into

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compositions comprising solid, semi-solid or liquid cosmetically and/or physiologically acceptable vehicles (col. 5, lines 60-64; col. 6, lines 7-22). Further, Jackson *et al.* teaches kits comprising the compositions, including packaging in a bottle or propellant-driven aerosol device (col. 13, lines 33-50). With respect to the instantly claimed ratio of 1:1, it would have been obvious to one of ordinary skill in the art to vary the ratio of the components in the compositions disclosed in Jackson *et al.* in order to formulate the most effective inhibition of the ceramide pathway. Such optimization is well within the purview of the skilled artisan.

The preambles of the instant claims recite intended uses, *e.g.* “An anti-cancer composition...” (Claim 1), and are viewed as non-limiting since they do not recite essential steps “necessary to give life, meaning and vitality” to the claimed subject matter. *Pitney Bowes*, 61 USPQ2d at 1165-66; *Kropa v. Robie*, 88 USPQ 478, 480-81 (CCPA 1951). The body of the claims following the preamble are self-contained descriptions of the invention (“...composition comprising N,N-dimethylphytosphingosine as an active ingredient”) and do not depend on the preamble for completeness. Accordingly, even when prior art compositions are used to treat other indications or inhibit other pathways, they anticipate the instantly claimed compositions because they recite a composition comprising the instantly claimed compound.

In the absence of a showing of the criticality of the instantly claimed ratio of 1:1, the instantly claimed compositions and kits would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Jackson *et al.* provide the means, suggestion and motivation to formulate a composition comprising N,N-dimethylphytosphingosine and other ceramide pathway inhibitors, including the instantly claimed phytosphingosine, acetylated phytosphingosine, and ethylated phytosphingosine.

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Accordingly, the claims are deemed properly rejected as being obvious over Jackson *et al.*


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


James D. Anderson
Patent Examiner
AU 1614

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June 5, 2007

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER
6/5/07